

<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> ( Not for submission under 37 CFR 1.99)	Application Number		09890335
	Filing Date		2002-04-08
	First Named Inventor	Cevc	
	Art Unit	1645	
	Examiner Name	B.J. Gangle	
	Attorney Docket Number		

## U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code <sup>1</sup>	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	4619794		1986-10-28	Hauser et al.	
	2	4746509		1988-05-24	Haggiage et al.	
	3	4783450		1988-11-08	Fawzi et al.	
	4	4849224		1989-07-18	Chang et al.	
	5	4937078		1990-06-26	Mezei et al.	
	6	4954345		1990-09-04	Muller et al.	
	7	4983395		1991-01-08	Chang et al.	
	8	5145684		1992-09-08	Liversidge et al.	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevc	
Art Unit	1645	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

9	5154930	1992-10-13	Popescu et al.	
10	5202125	1993-04-13	Ebert et al.	
11	5238613	1993-08-24	Anderson	
12	5244678	1993-09-14	Legros et al.	
13	5460820	1995-10-24	Ebert et al.	
14	5498418	1996-03-12	Beutner et al.	
15	5510118	1996-04-23	Bosch et al.	
16	5552160	1996-09-03	Liversidge et al.	
17	5607692	1997-04-04	Ribier et al.	
18	5614178	1997-03-25	Bloom et al.	
19	5648095	1997-07-15	Illum et al.	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevc	
Art Unit	1645	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

20	5654337	1997-08-05	Roentsch et al.	
21	5681849	1997-10-08	Richter et al.	
22	5716638	1998-02-10	Touitou et al.	
23	5741515	1998-04-21	Ciceri et al.	
24	5783208	1998-07-21	Venkateshwaran et al.	
25	5858330	1999-01-12	Boltri et al.	
26	5874095	1999-02-23	Deckner et al.	
27	5874422	1999-02-23	Krause et al.	
28	5958379	1999-09-28	Regenold et al.	
29	5985860	1999-11-16	Toppo	
30	6045827	2000-04-04	Russell	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevc	
Art Unit	1645	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

31	6069172		2000-05-30	Bertini et al.	
32	6193996		2001-02-27	Effing et al.	
33	6214386		2001-04-10	Santus et al.	
34	6276598		2001-08-21	Chi Cheng	
35	6277892		2001-08-21	Deckner et al.	
36	6294192		2001-09-25	Patel et al.	
37	6303141		2001-10-16	Fischer et al.	
38	6387383		2002-05-14	Dow et al.	

If you wish to add additional U.S. Patent citation information please click the Add button.

**U.S.PATENT APPLICATION PUBLICATIONS**

Examiner Initial*	Cite No	Publication Number	Kind Code*	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1	20010012849	A1	2001-08-09	Wechter	

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevc	
Art Unit	1845	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

2	20020003179	A1	2002-01-10	Verhoff et al.	
3	20020012680	A1	2002-01-31	Patel et al.	
4	20020037877	A1	2002-03-28	Singh	
5	20020106345	A1	2002-08-08	Uhrich et al.	
6	20020119188	A1	2002-08-29	Niemiec et al.	
7	20020147238	A1	2002-10-10	Jerussi et al.	
8	20030099694	A1	2003-05-29	Cevc et al.	
9	20040105881	A1	2004-06-03	Cevc et al.	
10	20050123897	A1	2005-06-09	Cevc et al.	
11	20070031483		2007-02-08	Cevc	
If you wish to add additional U.S. Published Application citation information please click the Add button.					
<b>FOREIGN PATENT DOCUMENTS</b>					

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

( Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevc	
Art Unit	1645	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

Examiner Initial*	Cite No	Foreign Document Number <sup>3</sup>	Country Code <sup>2</sup> j	Kind Code <sup>4</sup>	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
	1	724218	AU		2000-09-14	IDEA		<input type="checkbox"/>
	2	1740283	AU		1983-07-28	Ciba Geigy AG		<input type="checkbox"/>
	3	1143556	CA		1983-03-29	Kureha Kagaku Kogyo Kabushiki Kaisha		<input type="checkbox"/>
	4	2067754	CA		1992-02-25	IDEA AG		<input type="checkbox"/>
	5	2160775	CA		1994-11-24	Merck Patent GMBH, et al.		<input type="checkbox"/>
	6	1289420	CA		1991-09-24	Micro-Pak Inc.		<input type="checkbox"/>
	7	3713494	DE		1987-10-29	L'Oreal		<input checked="" type="checkbox"/>
	8	3016976	DE		1980-11-13	Kureha Kagaku Kogyo		<input checked="" type="checkbox"/>
	9	0152379	EP		1985-08-21	Ciba Geigy AG		<input checked="" type="checkbox"/>
	10	0382716	EP		1998-01-28	Warner-Lambert Co.		<input type="checkbox"/>

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevc	
Art Unit	1645	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

11	1031347	EP	2002-04-17	IDEA AG	<input type="checkbox"/>
12	0088046	EP	1983-09-07	Ciba Geigy Ag	<input checked="" type="checkbox"/>
13	0995435	EP	2000-04-26	Senju Pharmaceutical Co., Ltd.	<input type="checkbox"/>
14	0280492	EP	1988-08-31	Takeda Chemical Industries, Ltd.	<input type="checkbox"/>
15	0355095	EP	1993-08-04	The Liposome Company, Inc.	<input type="checkbox"/>
16	0211647	EP	1987-02-25	Allergan Pharmaceuticals, Inc.	<input type="checkbox"/>
17	0224837	EP	1986-11-24	Rohm Pharma GmbH	<input checked="" type="checkbox"/>
18	0674913	EP	1995-04-10	LecTec Corporation	<input type="checkbox"/>
19	0582239	EP	1994-02-09	Rhone-Poulenc Rorer GMBH	<input checked="" type="checkbox"/>
20	0393707	EP	1990-10-24	Otsuka Pharmaceutical Co.	<input type="checkbox"/>
21	07-324029	JP	1995-12-12	L'Oreal SA	<input checked="" type="checkbox"/>

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevco	
Art Unit	1645	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

22	61-271204	JP	1986-12-01	Shiseido Co. Ltd.		<input checked="" type="checkbox"/>
23	91/04013	WO	1991-04-04	Micro Vesicular Systems, Inc.		<input type="checkbox"/>
24	88/07362	WO	1988-10-06	Liposome Technology, Inc.		<input type="checkbox"/>
25	90/09782	WO	1990-09-07	Liposome Technology, Inc.		<input type="checkbox"/>
26	01/01963	WO	2001-01-11	IDEA AG		<input type="checkbox"/>
27	98/07414	WO	1998-02-26	Research Triangle Pharmaceuticals, Ltd.		<input type="checkbox"/>
28	96/04526	WO	1996-02-15	Siemens Automotive Corporation		<input type="checkbox"/>
29	02/07767	WO	2002-01-31	Alcon Universal Ltd.		<input type="checkbox"/>
30	02/11683	WO	2002-02-14	Dow Pharmaceutical Sciences		<input type="checkbox"/>
31	00/00597	WO	2000-01-06	The University of Manitoba		<input type="checkbox"/>
32	96/19205	WO	1996-06-27	Theratech, Inc.		<input type="checkbox"/>



**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevc	
Art Unit	1645	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

33	01/12155	WO		2001-02-22	Lipocine, Inc.		<input type="checkbox"/>
34	04/032900	WO		2004-04-22	IDEA AG		<input type="checkbox"/>
35	96/29999	WO		1996-10-03	Hexal AG		<input checked="" type="checkbox"/>
36	01/00247	WO		2001-01-04	The Liposome Company, Inc.		<input type="checkbox"/>
37	00/25822	WO		2000-05-11	John C. Grasela, et al.		<input type="checkbox"/>
38	00/44349	WO		2000-08-03	IDEA AG		<input type="checkbox"/>
39	98/05539	WO		1998-02-12	Toyota Jidosha Kabushiki Kaisha		<input checked="" type="checkbox"/>
40	00/44350	WO		2000-08-03	IDEA AG		<input type="checkbox"/>
41	00/50007	WO		2000-08-31	Lipocine, Inc.		<input type="checkbox"/>
42	98/24407	WO		1998-06-11	L'Oreal		<input checked="" type="checkbox"/>
43	98/06750	WO		1998-02-19	Keygene N.V.		<input type="checkbox"/>

# **INFORMATION DISCLOSURE STATEMENT BY APPLICANT**

(Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevc	
Art Unit	1645	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

44	87/01938	WO		1987-04-09	The Regents of the University of California		<input type="checkbox"/>
45	95/35095	WO		1995-12-28	Yissum Research Development Co-Hebrew U. Jerusalem		<input type="checkbox"/>
46	02/058670	WO		2002-06-01	Euroceltique S.A.		<input type="checkbox"/>
47	91/01596	WO		1991-02-07	SHAH, Reza H.		<input type="checkbox"/>
48	98/30215	WO		1998-07-16	Cilag AG		<input type="checkbox"/>
49	92/22292	WO		1992-12-23	Schwarz Pharma AG		<input checked="" type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

## **NON-PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
	1	(no entry)	<input type="checkbox"/>
	2	(no entry)	<input type="checkbox"/>
	3	Holum, Elements of General and Biological Chemistry: John Wiley & Sons, USA (1987), pages 324, 325	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevc	
Art Unit	1645	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

4	Stryer, Biochemistry: W.H. Freeman & Co., San Francisco, California, USA (1981), pages 208, 209	<input type="checkbox"/>
5	Mathews & van Holde, Biochemistry: The Benjamin/Cummings Publishing Co., Redwood City, California (1990), pages 303, 304	<input type="checkbox"/>
6	Agerholm, C., et al., "Epithelial transport and bioavailability of intranasally administered human growth hormone formulated with the absorption enhancer didecanoyl-L- $\alpha$ -phosphatidylcholine and $\alpha$ -cyclodextrin in rabbits." J. Pharm. Sci. 83(12): 1706-11 (Dec. 1994)	<input type="checkbox"/>
7	Aungst et al., "Enhancement of naloxone penetration through human skin in vitro using fatty acids, fatty alcohols, surfactants, sulfoxides and amides," on International Journal of Pharmaceutics 33:225-234 (1986)	<input type="checkbox"/>
8	(no entry)	<input type="checkbox"/>
9	Berger, M. "Oral insulin 1922-1992: The history of continuous ambition and failure" Heinrich-Heine-University, Dusseldorf, Germany, pages 144-148	<input type="checkbox"/>
10	Beyer, C. et al., "Micro Emulsions" Pharmazie in unserer Zeit. No. 2 (1983), pages 55-60	<input type="checkbox"/>
11	Blume et al., "Drug-carrier and stability properties of the long-lived lipid vesicles: cryptosomes, in vitro and in vivo" J. Liposome Research 2(3):355-368 (1992)	<input type="checkbox"/>
12	Brendzel, A. et al., "Effects of lipid-soluble substances on the thermotropic properties of liposome filtration" Biochimica et Biophysica Acta, 601:260-270 (1980)	<input type="checkbox"/>
13	Burnette, R. et al., "Characterization of the Permselective Properties of Excised Human Skin During Iontophoresis," J. Pharmaceutical Sciences 76(10):765-773 (Oct. 1987)	<input type="checkbox"/>
14	Byas-Smith et al., "Transdermal clonidine compared to placebo in painful diabetic neuropathy using two stage 'enriched enrollment' design," Pain 60:267-274 (1995)	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
( Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevc	
Art Unit	1645	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

15	Calpena, et al., "Influence of the Formulation on the In Vitro Transdermal Penetration of Sodium Diclofenac" <i>Arzneim-Forsch/Drug Res</i> 49(II):1012-1017 (1999)	<input type="checkbox"/>
16	Carafa M., et al., "Lidocaine-loaded non-ionic surfactant vesicles: characterization and in vitro permeation studies" <i>International J. of Pharmaceutics</i> 231:21-32 (2002)	<input type="checkbox"/>
17	Castillo et al., "Glucocorticoids prolong rat sciatic nerve blockade in vivo from bupivacaine microspheres," <i>Anesthesiology</i> 85(5):1157-66 (1996)	<input type="checkbox"/>
18	Cevc, et al., " Phospholipids handbook", Marcel Dekker, Inc., New York, Basel, Hong Kong, Chaps. 11, 12 pages 351-454; including pp.375-376 and 404 (1993)	<input type="checkbox"/>
19	Cevc, et al., "Transdermal drug carriers: basic properties, optimization and transfer efficiency in the case of epicutaneously applied peptides," <i>J. Contr. Rel.</i> 36:3-16 (1995)	<input type="checkbox"/>
20	Cevc, G. et al., "New, highly efficient formulation of diclofenac for the topical, transdermal administration in ultradeformable drug carriers, transfersomes," <i>Biochimica et Biophysica Acta</i> 1514:191-205 (2001)	<input type="checkbox"/>
21	Cevc, G. et al., "The skin: a pathway for systemic treatment with patches and lipid-based agent carriers" <i>Advanced Drug Delivery Reviews</i> 18:349-378 (1996)	<input type="checkbox"/>
22	(no entry)	<input type="checkbox"/>
23	Cevc, G. et al., "Material Transport Across Permeability Barriers by Means of Lipid Vesicles", <i>Handbook of Biological Physics</i> , Vol. 1, pp. 465-490 (1995)	<input type="checkbox"/>
24	Claims (pending as of about August 8, 2007) filed February 9, 2007 in US 09/555,986, under examination by Examiner Kishore	<input type="checkbox"/>
25	Claims (pending as of about August 8, 2007) filed May 8, 2007 in US 11/667,325	<input type="checkbox"/>

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevc	
Art Unit	1645	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

26	Claims (pending as of about August 8, 2007) filed February 26, 2007 in US 10/984,450 (US 2005/0123897), under examination by Examiner Fortuna	<input type="checkbox"/>
27	Claims (pending as of about August 8, 2007) filed January 22, 2007 in US 10/037,480 (US 2003/0099694), under examination by Examiner Fortuna	<input type="checkbox"/>
28	Claims (pending as of about August 8, 2007) filed July 12, 2007 in US 09/284,683 (US 2002/0048596, under examination by Examiner Kishore	<input type="checkbox"/>
29	Claims (pending as of about August 8, 2007) filed June 20, 2007 in US 10/357,618 (US 2005/0105881), under examination by Examiner Ghali	<input type="checkbox"/>
30	Claims (pending as of about August 8, 2007) filed October 11, 2006 in US 11/545,904 (US 2007/0031483), under examination by Examiner Ghali	<input type="checkbox"/>
31	Claims (pending as of about August 8, 2007) filed October 20, 2006 in US 10/357,617 (US 2004/0071767), under examination by Examiner Kishore	<input type="checkbox"/>
32	Clark, J.M., Jr. "Experimental Biochemistry," Biochemistry Division, Department of Chemistry, University of Illinois, pages 47-48	<input type="checkbox"/>
33	Copy of International Search Report for International Patent Application No. PCT/EP2005/011986 (July 4, 2006)	<input type="checkbox"/>
34	Definition of Microbicide, Wikipedia, The Free Online encyclopedia (2007)	<input type="checkbox"/>
35	Edwards, et al., "Effects of Triton X-100 on Sonicated Lecithin Vesicles," Langmuir 5:473-478 (1989)	<input type="checkbox"/>
36	Fieser, L.F. et al. "Organische Chemie," Hans Ruprecht Hensel, 2nd revised edition, Verlag Chemie GmbH, Weinheim/Bergstr. page 1250 (1968)	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**  
(Not for submission under 37 CFR 1.99)

Application Number		09890335
Filing Date		2002-04-08
First Named Inventor	Cevc	
Art Unit	1645	
Examiner Name	B.J. Gangle	
Attorney Docket Number		

37	FLUKA Chemica-BioChemica, Katalog 16, pages 204, 830 (1988/1989)	<input type="checkbox"/>
38	Foldvari, "Effect of vehicle on topical liposomal drug delivery: petrolatum bases," J. Microencapsulation, 13(5):589-600 (1996)	<input type="checkbox"/>
39	Foldvari, "In vitro cutaneous and percutaneous delivery and in vivo efficacy of tetracaine from liposomal and conventional vehicles," Pharmaceutical Research 11(11):1593-98 (1994)	<input type="checkbox"/>
40	Foldvari, et al., "Dermal drug delivery by liposome encapsulation: clinical and electron microscopic studies," J. Microencapsulation 7(4):479-489 (1990)	<input type="checkbox"/>
41	Frantzen et al., "Assessing the accuracy of routine photon correlation spectroscopy analysis of heterogeneous size distributions," AAPS PharmSciTech 4(3), Article 36:1-9 (2003)	<input type="checkbox"/>
42	Friedrich, I. et al., "Physicochemical characterization of a reverse micellar solution after loading with different drugs," Pharmazie 55(2000) 10, 755-758	<input type="checkbox"/>
43	Gesztes, A. et al., "Topical Anesthesia of the Skin by liposome-encapsulated tetracaine," Anesth. Analg 67:1079-1081 (1988)	<input type="checkbox"/>
44	Golden et al., "Role of stratum corneum lipid fluidity transdermal drug flux," on J. of Pharmaceutical Sciences, American Pharmaceuticals Association 76(1):25-28 (Jan. 1987)	<input type="checkbox"/>
45	Grahame R., "Transdermal non-steroidal anti-inflammatory agents," BJCP 49(1):33-35 (Jan-Feb 1995)	<input type="checkbox"/>
46	Green et al., "In vitro and in vivo enhancement of skin permeation with oleic and lauric acids," on International Journal of Pharmaceuticals 48:103-111 (1988)	<input type="checkbox"/>
47	Helenius, et al., "Solubilization of membranes by detergents," BBA 415:29-79 (1975)	<input type="checkbox"/>

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT****( Not for submission under 37 CFR 1.99)**

Application Number	09890335
Filing Date	2002-04-08
First Named Inventor	Cavc
Art Unit	1645
Examiner Name	B.J. Gangle
Attorney Docket Number	

48	Henmi, T. et al., "Application of an oily gel formed by hydrogenated soybean phospholipids as a percutaneous absorption-type ointment base," Chem. Pharm. Bull. 42(3) 651-655 (1994)	<input type="checkbox"/>
49	Ito, Yoshimasa et al., "Percutaneous absorption of acetaminophen from a membrane controlled transdermal system and prediction of the disposition of the drug in rats," Biol. Pharm. Bull. 16(6):583-88 (1993)	<input type="checkbox"/>

If you wish to add additional non-patent literature document citation information please click the Add button

**EXAMINER SIGNATURE**

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> See Kind Codes of USPTO Patent Documents at [www.USPTO.GOV](http://www.USPTO.GOV) or MPEP 901.04. <sup>2</sup> Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>3</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>4</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>5</sup> Applicant is to place a check mark here if English language translation is attached.